



101438-2 / Rubin 201-KGB

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1630

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT : DR. BERISH RUBIN ET AL.  
SERIAL NO. : 10/050,189  
FILED : January 16, 2002  
FOR : DETECTION OF MUTATIONS IN A GENE ENCODING IKB KINASE  
COMPLEX- ASSOCIATED PROTEIN TO DIAGNOSE FAMILIAL  
DYSAUTONOMIA  
ART UNIT : 1645  
EXAMINER : To Be Assigned

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Hon. Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

SIR:

Pursuant to 37 CFR §§ 1.56, 1.97 and 1.98, Applicants respectfully request that the Examiner consider the references listed on the attached Form PTO-1449.

**I. Timeliness, Fees and Certifications in lieu of Fees**

- ☒ A. This information disclosure statement is being filed within three months of the filing date of the application, or within three months of entry into the national stage, or before the mailing of a first Office Action on the merits. Pursuant to 37 CFR § 1.97(b), consideration of this information disclosure statement does not require a fee or a statement under 37 CFR § 1.97(e). However, should the Assistant Commissioner determine that a fee is, in fact, due, the Assistant Commissioner is hereby authorized to charge the fee to Deposit Account No. 14-1263.

- ☒ B. This information disclosure statement is being filed after the period in A above, but before the mailing of either a final action or a notice of allowance. Pursuant to 37 CFR § 1.97(c), consideration of this information disclosure statement requires a fee or a statement under 37 CFR § 1.97(e):
- ☒ 1. The Assistant Commissioner is hereby authorized to charge the fee set forth in 37 CFR § 1.17(p) to Deposit Account No. 14-1263.
- ☐ 2. Applicants hereby state that each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
- ☐ 3. Applicants hereby state that no item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 CFR § 1.56 more than three months prior to the filing of this information disclosure statement.
- ☐ C. This information disclosure statement is being filed after the period specified in B above, but on or before the payment of the issue fee. Pursuant to 37 CFR § 1.97(d), consideration of this information disclosure statement requires a petition, which Applicants hereby request, and payment of the petition fee, which is set forth in 37 CFR § 1.17(i), and which the Assistant Commissioner is hereby authorized to charge to Deposit Account No. 14-1263. Consideration of

this information disclosure statement also requires a statement under 37 CFR § 1.97(e):

- ☐ 1. Applicants hereby state that each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
- ☐ 2. Applicants hereby state that no item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 CFR § 1.56 more than three months prior to the filing of this information disclosure statement.

## **II. Copies of Listed References**

- ☒ A. Copies of all references listed on the attached Form PTO-1449 are being supplied.
- ☐ B. Copies of all references listed on the attached Form PTO-1449 have already been supplied during the prosecution of prior application Serial No. \_\_\_\_\_, filed \_\_\_\_\_, from which the present application claims priority pursuant to 35 USC § 120. Therefore, pursuant to 37 CFR § 1.98(d), copies of the references listed on the attached Form PTO-1449 are not now being supplied.
- ☐ C. This application is a PCT national stage application, all references listed on the attached Form PTO-1449 were cited in the international search report, and PCT/DO/EO/903 indicates that both the international search report and the copies

of the references listed on the attached Form PTO-1449 are in this national stage file. Therefore, copies of the references listed on the attached Form PTO-1449 are not now being supplied.

### III. Concise Statement of Relevance

- ☐ A. All references listed on the attached Form PTO-1449 are in the English language, and, therefore, a concise statement of relevance is not required.
- ☒ B. A concise statement of the relevance of all references listed on the attached Form PTO-1449 that are *not in the English language*, is provided below:  
FR 2 722 295: Abstract is enclosed.
- ☐ C. All references listed on the attached Form PTO-1449 were cited in the partial search report issued by the European Patent Office and/or the International search report, and an English-language version of the search reports, which indicates the degree of relevance found by that Patent Office, are attached.
- ☐ D. This application is a PCT national stage application, all references listed on the attached Form PTO-1449 were cited in the international search report, and a copy of that search report, which indicates the degree of relevance found by the International Search Authority, is attached.
- ☐ E. All listed on the attached Form PTO 1449 were cited during the prosecution of the prior application indicated above under II.B.

### IV. Additional Information

- ☐ A. In addition to the references listed on the attached Form PTO-1449, Applicants wish to bring to the attention of the Examiner the following abandoned

Application No. 10/050,189  
Applicant: DR. BERISH RUBIN ET AL.  
Information Disclosure Statement

or co-pending U.S. patent applications:


[Pursuant to 37 CFR § 1.98(a)(2)(iii), copies of these applications are not being submitted.]

- ☐ B. In addition of the references listed on the attached Form PTO-1449, Applicants wish to bring to the attention of the Examiner the information provided on the attached sheet.

Consideration of the foregoing in relation to this application is respectfully requested.

Respectfully submitted,

NORRIS McLAUGHLIN & MARCUS, P.A.

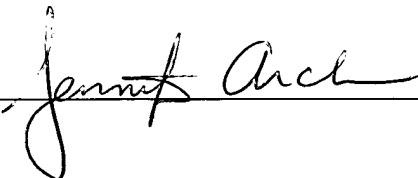
By   
David D. Kim  
Reg. No. 53,123

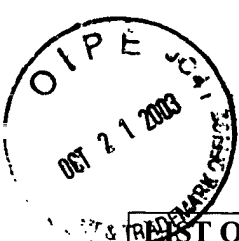
220 East 42<sup>nd</sup> Street  
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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Services as first class mail in an envelope addressed to: Hon. Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on October 17, 2003

NORRIS McLAUGHLIN & MARCUS, P.A.

By 



<b>UNITED STATES PATENT AND TRADEMARK OFFICE</b> <b>APPLICANT'S INFORMATION</b> <b>DISCLOSURE STATEMENT</b> (Form PTO-1449)	Attorney Docket: 101438-2/ Rubin 201-KGB	Serial No.: 10/050,189
	Applicant: DR. BERISH RUBIN ET AL.	
	Filing Date: January 16, 2002	Group: 1645

**U.S. PATENT DOCUMENTS**

Examiner's Initial		Document Number	Date	Name	Class	Sub Class	Filing Date If appropriate
	AA	5,891,719	6 Apr 1999	Cohen et al.	435	325	
	AB	2002 / 0169299 A1	14 Nov 2002	Slaughaupt et al.	536	23.1	
	AC	6,262,250 B1	17 Jul 2001	Blumenfeld et al.	536	24.33	
	AD	2002 / 0025528 A1	28 Feb 2002	Blumenfeld et al.	435	6	

**FOREIGN PATENT DOCUMENTS**

		Document Number	Date	Country	Class	Sub Class	Translation Yes No
	AH	02 / 059381 A1	1 Aug 2002	World			
	AI	2 722 295 A1	12 Jan 1996	France			
	AJ	93/24657	9 Dec 1993	World			
	AK	01/68917 A1	20 Sept 2001	World			

**OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)**

	AL	Cuajungco, Math P. et al., "Cloning, Characterization, and Genomic Structure of the Mouse Ikpkap Gene", DNA and Cell Biology, Vol. 20, No. 9, September 2001, pgs. 579-586.
	AM	Coli, Rocco et al., "Genomic organization and chromosomal localization of the mouse IKBKAP gene", Gene, 279 (2001): 81-89.
	AN	Slaughaupt, Susan A. et al., "Tissue-Specific Expression of a Splicing Mutation in the IKBKAP Gene Causes Familial Dysautonomia", Am. J. Human Genetics, Vol. 68 (2001), pgs. 598-605.
	AO	Anderson, Sylvia et al., "Familial Dysautonomia is Caused by Mutations in the IKAP Gene", Am. J. of Human Genetics, Vol. 68 (2001), pgs. 753-758.
	AP	Cohen, Lucie et al., "IKAP is a scaffold protein of the Ikb kinase complex", Nature, Vol. 395, 17 September 1998, pgs. 292-296.
	AQ	Blumenfeld Anat et al., "Precise Genetic Mapping and Haplotype Analysis of the Familial Dysautonomia Gene on Human Chromosome 9q31", Am. J. of Human Genetics, Vol. 64 (1999), pgs. 1110-1118.
	AR	Abstract of FR 2722295 from EPO website database.
	AS	EPO Search Report dated 10 February 2003 of EP 02 00 1232.

**EXAMINER:****DATE CONSIDERED:**

- **EXAMINER:** Initial if Reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformation and not considered, include copy of this form with next communication to applicant.